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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,160	09/29/2003	William T. Donofrio	END-5030	1906
27777	7590	12/23/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ROY, ANURADHA	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/674,160	Applicant(s) DONOFRIO ET AL.	
	Examiner Anuradha Roy	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,7,&16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,& 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restrictions

Claims 3, 6, 7, & 16-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Election was made without traverse in the reply filed on 9 December 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 2, 4, 9, 10, & 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hickie (US Patent No. 6,745,764).

Regarding claims 1, 12, & 15, Hickie discloses a conscious sedation system comprising: a) a controller (14) which generates a request for a predetermined hand grip response (Column 21, lines 33-44) from a patient and which analyses at least a dynamic variable of a hand grip response made by the patient to the request to determine a level of sedation of the patient and b) a response testing apparatus (256, 264, & 266) including: a request assembly (256 & 264) which communicates to the

patient the request generated by the controller; and a response assembly (256 & 254) which senses the dynamic variable of the hand grip response and which communicates the dynamic variable to the controller.

With regard to claims 2 & 14, Hickle discloses a conscious sedation system, wherein a user and/or the controller determines a delivery schedule of a conscious-sedation drug to the patient based at least in part on the determined level of sedation of the patient (Column 21, lines 45-67).

Regarding claim 4, Hickle discloses a conscious sedation system, wherein the response assembly includes a handpiece (55), which is disposable in a hand of the patient, which senses the dynamic variable (Column 21, lines 45-52), and which communicates the dynamic variable to the controller (Column 21, lines 45-58).

In regard to claim 9, Hickle discloses a conscious sedation system, wherein the controller generates a feedback signal (Column 21, lines 45-49), which is communicated to the patient when the hand grip response from the patient meets a predetermined criteria.

In regard to claim 10, Hickle discloses a conscious sedation system, wherein the controller changes the predetermined criteria between two requests and at least

analyzes the hand grip responses from the two requests to determine the level of sedation of the patient (Column 25, lines 57-67).

With regard to claim 13, Hickle discloses a response testing apparatus, wherein the dynamic variable is chosen from the group consisting of the amount of force of the hand grip response, the time variation of the amount of force of the time grip response, the distance of the hand grip response, the velocity of the hand grip response, and the acceleration of the hand grip response (Column 21, lines 45-67). Examiner contends the determination of the time taken to respond with the hand piece and the distance the hand held member moves directly relates to the velocity of the hand grip response and thus determines what Hickle discloses as “ latency period.”

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 8, & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Hickle in view of Symser et al. (US Patent No. 5,904,639).

Hickle discloses the aforementioned elements of a conscious sedation system. However, Hickle does not disclose a system wherein the handpiece senses the force of the hand grip response. Symser et al., however, teaches of a system, wherein the handpiece includes a force sensor (Column 3, lines 32-36), and wherein the controller at least analyzes at least one of the amount of force of the hand grip response and the time variation of the amount of force of the hand grip response (Column 3, lines 32-36 & Column 14, lines 38-56) and is capable of determining the level of sedation of the patient. Additionally, Symser et al. discloses a handpiece that is adjustable to respond to one of a lower hand grip force and a higher hand grip force (Column 3, lines 64-67). It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Symser et al. to include a handpiece with a force sensor with Hickle in order to determine the consciousness of a sedated person.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tsutsumi et al. (US Patent No. 6,315,736) discloses a system to monitor the anesthetic depth of a patient. Lewis, Jr. (US Patent No. 5,329,813 & 5,157,970) and Kovacevic (US Patent No. 5,125,270) both disclose hand grip analysis

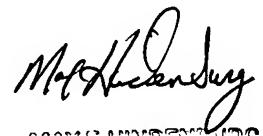
Art Unit: 3736

systems and methods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~


MAX HINDENBURG
SUPERVISOR
ART UNIT 3736